

REMARKS

The Office Action dated June 3, 2003 has been carefully considered. Claims 1-4, 11, and 12 are pending in the present application. Claims 5-10 and 13-44 have been withdrawn. Applicant fully reserves the right to prosecute the subject matter of the non-elected claims in a subsequent application. Reconsideration of the present application in view of the following remarks are respectfully requested.

I. CLAIM REJECTIONS UNDER 35 U.S.C. § 102(e)

Claims 1 and 12 have been rejected under 35 U.S.C. § 102(e) as allegedly being anticipated by U.S. Patent No. 6,562,065 to Shanley ("Shanley"). This rejection is respectfully traversed.

Independent claim 1 recites a "medical device for delivering a biological active material to a body tissue of a patient in need of treatment, wherein the medical device comprises a plurality of struts and a plurality of non-structural elements integral with the struts, wherein the struts and the non-structural elements comprise the biologically active material." (Emphasis added). Claim 12 depends upon claim 1 and therefore includes all of the recitations of claim 1.

Shanley does not disclose or suggest "non-structural elements integral with the struts" as recited in the present claims. As stated in the specification, the non-structural elements have substantially no effect on the mechanical properties of the stent. Moreover, the non-structural elements of the present invention can project from the strut or can be located along the strut. (See, e.g., page 8, line 20 of the specification). In addition, the non-structural elements can be used to increase the surface area of the stent, and thus vary the distribution of the biologically active material. (Page 15, lines 1-6 of the specification). In addition, the non-structural elements comprise the biologically active material. (Page 7, lines 30-31 of the specification). Also, the "non-structural elements are integral with the struts, namely, they are generally made from the same material as the struts and are formed as a continuous part of the struts." (Page 8, lines 24-26 of the specification).

In contrast, Shanley teaches struts that have laser drilled holes therein for containing a beneficial agent. (Col. 14, lines 50-51). Figure 11 of Shanley shows a laser drilled hole 182 in the strut 88. Thus, Shanley merely removes material from the strut and, thus, does not disclose or suggest the inclusion of non-structural elements integral with the struts as recited in the present claims. It is respectfully submitted that the "hole" disclosed in Shanley is not a non-structural element and therefore cannot be considered to be a non-structural element

integral with a strut. By disclosing laser drilled holes in the struts to remove material from the struts, Shanley teaches away from the medical device of the present invention which includes, in addition to the struts, non-structural elements integral with the struts. Moreover, Shanley does not disclose or suggest any elements that project from the struts or are located along the struts of its devices.

Even assuming for the sake of argument that the holes 182 are non-structural elements, which they are not, Shanley does not disclose or suggest that the struts and the non-structural elements comprise the biologically active material. Shanley discloses that the agents can be disposed “on the struts or within the struts.” (Col. 14, lines 45-48). However, Shanley does not disclose or suggest that both the struts themselves comprise an agent and that the holes also contain the agent. As stated above, Shanley does not even disclose or suggest, and, in fact, teaches away from the use of non-structural elements.

Thus, it is believed that claim 1 and the claims depending thereon are patentable over Shanley. Accordingly, withdrawal of this rejection and allowance of claims 1 and 12, are respectfully requested.

II. CLAIM REJECTIONS UNDER 35 U.S.C. § 103(a)

A. Claims 3-4 Are Patentable Over Shanley

Claims 3 and 4 have been rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Shanley. This rejection is respectfully traversed.

Claims 3 and 4 depend upon claim 1 which recites that “the medical device comprises a plurality of struts and a plurality of non-structural elements integral with the struts, wherein the struts and the non-structural elements comprise the biologically active material.” Claim 3 further recites that “the non-structural elements are configured in a shape selected from the groups consisting of hoops, knots and bends, which are located along the stents.” Claim 4 further recites that the medical device “comprises a tubular portion comprising an outer surface, and wherein the non-structural elements are distributed throughout the outer surface.” Since claims 3 and 4 depend upon claim 1, which was shown above to be patentable over Shanley, it is believed that claims 3 and 4 are also patentable over Shanley. As stated above, Shanley does not even disclose or suggest, and, in fact, teaches away from the use of non-structural elements.

Additionally, the Examiner has stated that “[i]t is obvious to one having ordinary skill in the art that the “holes” (182) of Shanley can equate to “hoops” because both have a

circular shape.” (Office Action, page 3). In the present invention, the non-structural elements are integral with the struts and the struts as well as the non-structural elements *comprise* the biologically active material. The hoops of the present invention are non-structural elements that are integral with the struts, and as shown in Figure 8a, increase the surface area of the medical device. (*See also* Specification, page 8, lines 19-20). It is respectfully submitted that the “hole” disclosed in Shanley is an absence of material and therefore is not a non-structural element that is integral with a strut.

Thus, Shanley does not disclose or suggest (1) non-structural elements that are integral with the struts and (2) struts and non-structural elements that both comprise the biologically active material as required by the present claims.

Accordingly, it is believed that claim 1 and the claims depending thereon are patentable over Shanley. Thus, withdrawal of this rejection and allowance of claims 3 and 4 are respectfully requested.

**B. Claim 11 Is Patentable Over Shanley
In View Of U.S. Patent No. 6,506,437 to Harish *et al.***

Claim 11 has been rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Shanley in view of U.S. Patent No. 6,506,437 to Harish *et al.* (“Harish”). This rejection is respectfully traversed.

Claim 11 depends upon claim 1, which recites that “the medical device comprises a plurality of struts and a plurality of non-structural elements integral with the struts, wherein the struts and the non-structural elements comprise the biologically active material.” Claim 11 further recites that “the biologically active material is selected from the group consisting of paclitaxel, actinomycin, sirolimus, tacrolimus, everolimus, dexamethasone, halofuginone and hydrophobic nitric oxide adducts.” Since claim 1 was shown above to be patentable over Shanley, it is believed that claim 11, which depends upon claim 1, is also patentable over Shanley. As stated above, Shanley does not even disclose or suggest, and, in fact, teaches away from the use of non-structural elements.

Furthermore, Harish does not remedy the deficiencies of Shanley. Harish discloses a device that has depots formed in the outer surface thereof. (Col. 3, lines 32-33). Also, Harish discloses applying a composition including a therapeutic substance into the depots. (Col. 2, lines 19-20). However, the depots are not non-structural elements since they are formed from removal or absence of material in the outer surface. Thus, like Shanley, Harish does not disclose or suggest a non-structural element integral with the struts and therefore does not disclose non-structural elements comprising a biologically active material.

Thus, Shanley and Harish, taken alone or in combination, do not disclose or suggest (1) non-structural elements that are integral with the struts and (2) struts and non-structural elements that both comprise the biologically active material as required by the present claims.

Accordingly, it is believed that claim 11 is patentable over Shanley and Harish. Thus, withdrawal of this rejection and allowance of claim 11 is respectfully requested.

III. ALLOWABLE SUBJECT MATTER

The Examiner has objected to claim 2 as allegedly being dependent upon a rejected base claim, but stated that claim 2 would be allowable if rewritten in independent form to include all of the limitations of the base claims and any intervening claims. Claim 2 depends upon claim 1 which was shown above to be allowable. Thus, it is believed that claim 2 is also allowable. Accordingly, Applicant respectfully requests withdrawal of this objection, and allowance of claim 2.

IV. CONCLUSION

Since all objections and rejections to the claims are believed to be overcome, all claims are believed to be in condition for allowance. An early notice to that effect would be appreciated. Should the Examiner not agree with Applicants' position, then a personal or telephonic interview is respectfully requested to discuss any remaining issues and expedite the eventual allowance of the application.

Respectfully submitted,

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Date: September 3, 2003

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